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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/805,806

03/22/2004

Jeffrey S. Kiel

455-026

9957

1009 7590 02/09/2007  
KING & SCHICKLI, PLLC  
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EXAMINER

OH, TAYLOR V

ART UNIT

PAPER NUMBER

1625

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/805,806	KIEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Taylor Victor Oh	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Applicant's arguments with respect to claims 1-19 have been considered but are moot in view of the new ground(s) of rejection.

### The Status of Claims

Claims 1-19 are pending.

Claims 1-19 are rejected.

### **DETAILED ACTION**

1. Claims 1-19 are under consideration in this Office Action.

#### **Priority**

2. It is noted that this application claims benefit of 60/457,399 (03/25/03).

#### **Drawings**

3. None.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-19 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17, and 19-29 of copending Application No. 10806,260. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim 1 is related to the process for preparing a gabapentin tannate by reacting gabapentin with tannic acid to produce a pharmaceutically effective amount of gabapentin tannate in solid dosage form, whereas the claim 1 of the copending Application No. 10806,260 is for the process for preparing a gabapentin tannate composition for treating a condition of the central nervous system in an mammalian subject by reacting gabapentin with tannic acid to produce a pharmaceutically effective amount of gabapentin tannate .

However, the instant invention differs from the prior art in that the phrase "for treating a condition of the central nervous system in an mammalian subject " is not incorporated into the process claims.

Even so, claim 17 describes the method of treating a condition of the central nervous system in an mammalian subject administering a pharmaceutically effective amount of gabapentin tannate in solid dosage form. From this, there is the only difference in the rearrangement or incorporation of the claim limitation into another claim. Therefore, it would have been obvious to the skillful artisan in the art to be motivated to rearrange the claims in such a way to emphasize the certain aspect of the

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claimed invention in the process because they are not patentably distinct from each other with respect to the claims of themselves.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-16 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 5-10,12,14, and 18-19 of copending Application No. 10806,022. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claim 1 is related to the process for preparing a gabapentin tannate by reacting gabapentin with tannic acid to produce a pharmaceutically effective amount of gabapentin tannate in solid dosage form wherein the tannic acid component is of either natural or synthetic origin, whereas the claims 5-6 of the copending Application No. 10806,022 is for the method of synthesizing gabapentin tannate by mixing gabapentin with tannic acid to obtain gabapentin tannate wherein the tannic acid component is of either natural or synthetic origin.

However, the instant invention differs from the prior art in that the usage difference of the weight of tannic acid and gabapentin is described in a proportion rather than a ratio in the claim.

Even so, concerning their respective range of tannic acid and gabapentin between them, they are overlapped with each other. Therefore, it would have been

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obvious to the skillful artisan in the art to be motivated to use the ratio instead of the proportion in the claims because they are not patentably distinct from each other with respect to the claims of themselves.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
TAYLOR VICTOR OH  
PRIMARY EXAMINER

2/3/07